K010921

JUN 2 5 2001

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is:

1. Date of summary: May 11, 2001

2. Submitted by: Advantage Diagnostics Corporation
1201 Douglas Ave
Redwood City CA 94063

3. Device Name: Advantage Marijuana (THC) Home Drug Test

4. Device Classification: Class II, Panel 91 Toxicology

5. Device description: The Advantage Marijuana (THC) Home Drug Test is an immunochromatographic based one step *in vitro* test for use at home.

6. Intended Use: The Advantage Marijuana (THC) Home Drug Test is designed for the qualitative determination of THC (cannabinoids) in human urine at a cut off level of 50ng/mL

The test is the first part of a two-step process to provide consumers with information regarding the presence or absence, of THC in a urine sample. Confirmation, using GC/MS, of any possible drug result is recommended as the second step.

7. Substantial Equivalence: The Advantage Marijuana (THC) Home Drug Test is substantially equivalent to several other professional and over the counter immunoassay Drugs of Abuse Tests, such as Phamatec QuickScreen™ At Home Test. Both home drug tests are the first of a two-step process to detect the presence or absence of drugs of abuse in human urine and require consumers to confirm possible positive results with GC/MS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 5 2001

Ms. Janis Freestone
Director, Regulatory Affairs
Advantage Diagnostics Corporation, Limited
1201 Douglas Avenue
Redwood City, CA 94063

Re: 510(k) Number: K010921
Trade/Device Name: Advantage Marijuana (THC) Home Drug Test
Regulation Number: 862.3870
Regulatory Class: II
Product Code: LDJ
Dated: May 11, 2001
Received: May 14, 2001

Dear Ms. Freestone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510k Number: K010921

Device Name:
Advantage Marijuana (THC) Home Drug Test

Indications for Use:

The Advantage Marijuana (THC) Home Drug Test is a qualitative, one step, immunochromatographic competitive assay used to screen human urine for the presence of THC at a cut off concentration of 50ng/mL.

The test is the first part of a two-step process to provide consumers with information regarding the presence or absence, of THC. Confirmation, using GC/MS, of a possible drug result is recommended as the second step.

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010921

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ (Per 21 CFR 801.109)

OR

Over the counter use ✓